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MEMORANDUM

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Angela Southwell, Paralegal Specialist

RE: Notice of Proposed Rulemaking
Rule 64B16-28.100

DATE: April 2, 2014

The above-referenced Notice was submitted to the Bureau of Administrative Code on February 19, 2014, for publication in the Florida Administrative Register on February 20, 2014. Enclosed is a copy for your records.

If you have any questions or concerns, please feel free to contact me.

Enclosure

cc: DOH General Counsel

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE NO.
64B16-28.100

RULE TITLE:
Pharmacy Permits -
Applications and Permitting.

PURPOSE AND EFFECT: The Board proposes the rule amendment to update form DH-MQA 1220 incorporated by reference into this rule consistent with Rule 64B16-28.810.

SUMMARY: The proposed rule amendment is necessary to make form DH-MQA 1220 incorporated by reference into this rule consistent with Rule 64B16-28.810.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST AND LEGISLATIVE

RATIFICATION: The agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency. The agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature because the changes to the rule text only update an incorporated form used for special permits, the changes to the incorporated form are at the request of JAPC to make the form consistent with rule 64B16-28.810, and the request of such a special permit by a pharmacy under rule 64B16-28.810 is optional. No person or interested party submitted additional information regarding the economic impact at that time. Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.022 FS.

LAW IMPLEMENTED: 456.013, 456.025(3), 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Tammy Collins, Acting Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at <http://www.doh.state.fl.us/mqa/pharmacy> or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at <http://www.FLHealthsource.com>. The application must be accompanied with a \$250 initial permit fee, payable to the Board.

(1) through (4) No Change.

(5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, “Special Pharmacy Permit Application and Information,” effective ~~December 2013~~ ~~August 2012~~, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02303>. <http://www.flrules.org/Gateway/reference.asp?No=Ref-02303>.

(a) through (d) No Change.

(6) through (8) No Change.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History—New 2-21-13, Amended 9-23-13, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy.

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Pharmacy.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 4, 2013

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: January 30, 2014.